10/537400-

Docket No.: A0345.0010

### JC17 Rec'd PCT/PTO

IN THE UNITED STATES PATENT AND TRADEMARK OFFI

In re Patent Application of:

Martin Bolli et al.

Application No.: Not Yet Assigned

Confirmation No.: N/A

Filed: Concurrently Herewith

Art Unit: N/A

For:

**NOVEL SULFAMIDES** 

Examiner: Not Yet Assigned

#### **INFORMATION DISCLOSURE STATEMENT (IDS)**

MS PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450 ---

Dear Sir:

Pursuant to 37 CFR 1.56, 1.97 and 1.98, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO/SB/08. It is respectfully requested that the information be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue therefrom.

For the Examiner's convenience, the references cited are included in PDF format on the enclosed CD Rom. The attached SB-08 form lists the file name for each document on the CD Rom. If the Examiner has any questions, he is welcome to contact the undersigned at the number below.

#### Timing of Filing of the Information Disclosure Statement:

 $\boxtimes$ This IDS is being filed before the First Office Action<sup>1</sup>.

<sup>&</sup>lt;sup>1</sup> The IDS should, where possible, include a certification under 37 C.F.R. §1.97(e).

10/537400

Applic	ation No.: Not Yet Assigned  Docket No.: A0345.0010  JC17 Rec'd PCT/PTO 0 2 JUN 2005
	This IDS is being filed after the issuance of the First Office Action but before the
	issuance of a Final Office Action <sup>2</sup> .
	This IDS is being filed after the submission of a Notice of Appeal, but before the payment of the Final Fee <sup>3</sup> .
Certif	ications:
If chec	cked, the undersigned makes the following statement(s):
	Statement under 37 CFR § 1.97(e):
	Each item of information contained in this information disclosure statement was
	first cited in any communication from a foreign patent office in a counterpart
	foreign application not more than three months prior to the filing of this
	information disclosure statement; or
	No item of information contained in this information disclosure statement was cited
	in a communication from a foreign patent office in a counterpart foreign
	application, and, to the knowledge of the undersigned after making reasonable
	inquiry, no item of information contained in this information disclosure statement
	was known to any individual designated in § 1.56(c) more than three months prior
	to the filing of the information disclosure statement.
	Statement Under 37 C.F.R. § 1.704(d):
	Each item of information contained in this information disclosure statement was
	cited in a communication from a foreign patent office in a counterpart application
	less than thirty days prior to the filing of this information disclosure statement.
\$1.17(p)	<sup>2</sup> The IDS must include either a certification under 37 C.F.R. §1.97(e) or the fee set forth in 37 C.F.R.
	<sup>3</sup> The IDS must include both a certification under 37 C.F.R. §1.97(e) and the fee set forth in 37 C.F.R.

§1.17(p).

10/537400 Docket No.: A0345.0010 JC17 Rec'd PCT/PTO 02 JUN 2005

	JOH NEC OPCIPED UZ JUN Z
Fee F	Required by 37 C.F.R. § 1.97(c)(2) or 1.97(d)(2):
	If checked, the fee of \$180.00 set forth in 37 C.F.R. \$1.17(p) is attached.
Copi	es of Information:
In acc	cordance with 37 C.F.R. §1.98(a), the following are enclosed:
$\boxtimes$	An electronic copy <sup>4</sup> of each document (or relevant portion thereof) cited in the attached PTO/SB/08 is included on the enclosed CD Rom in PDF format.
$\boxtimes$	A copy <sup>5</sup> of the document entitled H. Arai, et al.; Nature; 1990; Vol. 348; pg. 730 will be enclosed with a subsequent Information Disclosure Statement.
$\boxtimes$	With respect to any information which is not in English, a concise explanation of the relevance, as it is presently understood by the individual designated in $\S 1.56(c)$ most knowledgeable about the content of the information, is attached. This concise explanation is provided by way of:
	A translation of the relevant portions of the non-English language information <sup>6</sup> ;

<sup>&</sup>lt;sup>4</sup> A legible copy of the document is not required if (1) the information was previously cited by, or submitted to, the Office and considered by the Office in a prior U.S. application to which this application claims priority, provided that the prior application is properly identified in this IDS, and (2) the IDS submitted in the earlier application complies with 37 C.F.R. § 1.98(a) – (c). This exception does not apply to information cited in an International Application.

<sup>&</sup>lt;sup>5</sup> A legible copy of the document is not required if (1) the information was previously cited by, or submitted to, the Office and considered by the Office in a prior U.S. application to which this application claims priority, provided that the prior application is properly identified in this IDS, and (2) the IDS submitted in the earlier application complies with 37 C.F.R. § 1.98(a) – (c). This exception does not apply to information cited in an International Application.

<sup>&</sup>lt;sup>6</sup> 37 C.F.R. §1.98(a)(3)(ii) *requires* that an English language translation be provided when a translation of the document, or portion thereof, "is within the possession, custody or control of, or is readily available to any individual designated in 37 C.F.R. § 1.56(c)."

Application No.: Not Yet Assigned

Docket No.: A0345.0010

JC17 Rec'd PCT/PTO 0 2 JUN 2005

A statement explaining the relevant portions of the non-English
language information;
A copy [and, where not in the English language, a translation] of at
least the relevant portion(s) <sup>7</sup> of the communication from a foreign patent
office in a counterpart foreign application in which the information was
cited; or
This information is contained in the specification of the present application.
In accordance with 37 C.F.R. 1.98(d), copies of the cited documents are not
enclosed as they were provided in application Serial No, filed on
, which the present application relies upon for an earlier effective filing
date under 35 U.S.C. 120.

#### Materiality:

Whether or not the information and references disclosed in this Information Disclosure Statement is "material" pursuant to 37 CFR 1.56, this submission is not intended to constitute an admission that any patent, publication or other information referred to therein is "prior art" for this invention unless specifically designated as such.

In accordance with 37 CFR 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 CFR 1.56(a) exists.

<sup>&</sup>lt;sup>7</sup> The relevant portion is that portion which indicates the degree of relevance found by the foreign patent office. This may be an explanation of which portion of the of the reference is particularly relevant, to which claims it applies, or merely an "X", "Y", or "A" indication on a search report. MPEP §609 III A(3).

10/537400

Application No.: Not Yet Assigned

Docket No.: A0345.0010

JC17 Rec'd PCT/2TC 0 2 JUN 2005

It is submitted that the Information Disclosure Statement is in compliance with 37 CFR 1.98 and the Examiner is respectfully requested to consider the listed references.

In the event the actual fee is inadvertently not enclosed or if any additional fee during the prosecution of this application is not paid, the Patent Office is authorized to charge the underpayment to Deposit Account No. 50-2215.

Dated: June 2, 2005

Respectfully submitted,

Charles E. Miller

Registration No.: 24,576

DICKSTEIN SHAPIRO MORIN &

OSHINSKY LLP

1177 Avenue of the Americas

New York, New York 10036-2714

(212) 835-1400

Attorney for Applicant

CEM/IY/da

# JC17 Rec'd PCT/PTO 0 2 JUN 2005

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Suit	ostitute for form 1449A/B/P	TO		Complete if Known			
Suc	ostitute for form 144970B/F	.0		Application Number			
II.	NFORMATION	N DI	SCLOSURE	Filing Date	Concurrently Herewith		
S	TATEMENT	Application Number Not Yet Assigned 3 3 7 4 0 0  ON DISCLOSURE T BY APPLICANT  Application Number Not Yet Assigned 3 3 7 4 0 0  Filing Date Concurrently Herewith  First Named Inventor Martin Bolli  Art Unit N/A					
				Art Unit	N/A		
(Use as many sheets as necessary)				Examiner Name	Not Yet Assigned		
Sheet	1	of	3	Attorney Docket Number	A0345.0010		

			U.S. PA	TENT DOCUMENTS	-
Examiner Initials*	Cite No.1	Document Number  Number-Kind Code <sup>2</sup> ( <i>if known</i> )	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA	US-4,233,294	11-11-1980	Fritz Maurer, et al.;	On CD as filename US04233294B1.pdf.

		FOREI	GN PATENT	DOCUMENTS		
Examiner Initials*	Cite No.1	Foreign Patent Document  Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	ВА	EP-0 526 708-B1	10-18-2000	HOFFMANN LA ROCHE	On CD as filename EB00526708B1.pd f.	
	BB	EP-0 633 259-B1		HOFFMANN LA ROCHE	On CD as filename EB00633259B1.pd f.	
	BC	EP-0 658 548-B1	11-19-1997	TANABE SEIYAKU CO., LTD.	On CD as filename EB00658548B1.pd f.	
	BD	EP-0 743 307-B1	09-12-2001	TANABE SEIYAKU CO., LTD.	On CD as filename EB00743307B1.pd f.	
	BE	EP-0 882 719-B1	05-16-2001	YAMANOUCHI PHARMACEUTICAL CO., LTD.	On CD as filename EB00882719B1.pd f.	
	BF	EP-0 959 072-B1	09-25-2002	TANABE SEIYAKU CO., LTD.	On CD as filename EB00959072B1.pd f.	
	BG	FR-1,549,494	12-13-1968		On CD as filename FR1549494.pdf.	
	ВН	WO-02/053557-A1	07-11-2002	ACTELION PHARMACEUTICALS LTD	On CD as filename WO02053557A1.p df.	
	BI	WO-96/19459	06-27-1996	F. HOFFMANN-LA ROCHE	On CD as filename WO96019459A1.p df.	

Examiner	Date	
Signature	Consider	red

## JC17 Rec'd PCT/PTO 02 JUN 2005

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Sub	stitute for form 1449A/B/PT	·o	- · · · ·		Complete if Known
				Application Number	Not Yet Assigned 3 3 / 4 U
11	<b>IFORMATION</b>	1 DI	SCLOSURE	Filing Date	Concurrently Herewith
STATEMENT BY APPLICANT				First Named Inventor	Martin Bolli
				Art Unit	N/A
	(Use as many sh	eets as	necessary)	Examiner Name	Not Yet Assigned
Sheet	2	of	3	Attorney Docket Number	A0345.0010

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at <a href="https://www.uspto.gov">www.uspto.gov</a> or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

		NON PATENT LITERATURE DOCUMENTS	
Examiner Initials	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T²
	CA	Volker Breu, et al.; "In vitro characterization of RO 46-2005, a novel synthetic non-peptide	
		endothelin antagonist of ETA and ETB receptors"; FEBS 13244; Vol. 334(2); November 1993; pp. 210-214; On CD under filename Breu_20050526160232.pdf.	
	СВ	D. J. Brown, et al.; "Pyrimidine Reactions VI.* The Amination of Chloropyrimidines with n-Alkylamines"; Aust. J. Chem; 1964; 17, pp. 794-802; On CD as filename Brown 20050526162958.pdf.	
	CC	Elliott Cohen, et al.; "Sulfamoyl Chloride, Sulfamides and Sulfimide"; J. Am. Chem. Soc.; 1962; Vol. 84; pp. 1994-2002. On CD as filename Cohen_20050526162403.pdf.	
	CD	Donald G. Crosby, et al.; "n-Butyl 5-Chloro-2-pyrimidoxyacetate-A Plant Growth Regulator Analog"; J. Org. Chem.; 1960; Vol. 25; pp. 1916-1919. On CD as filename Crosby_20050526162918.pdf.	
	CE	Georges Dewynter, et al.; "Synthese de 'sulfahydantoines' chirales. Aspects stereochimiques et protection regiospecifique."; Tetrahedron; 1993; Vol. 49(1); pp. 65-76; On CD as filename Dewynter_20050526163615.pdf.	
	CF	Roger P. Dickinson, et al.; "Thromboxane Modulating Agents. 3. 1H-Imidazol-1-yulalkyl- and 3-Pyridinylalkyl-Substituted 3-[2-[Arylsulfonyl)amino]ethyl]benzenepropanoic Acid Derivatives as Dual Thromboxane Synthase Inhibitor/Thromboxane Receptor Antagonists"; J. Med. Chem.; 1997; Vol. 40; pg. 3442. On CD as filename Dickinson_20050526162822.pdf.	
	CG	Wolfgang, Gohring, et al.; "Development of a Process to Prepare 2-Cyanopyrimidine on Commercial Scale"; Chimia; 1996; Vol. 50; pp. 538-543; On CD as filename Goehring 20050526160404.pdf.	
	СН	Roderich Graf; "Umsetzungen mit N-Carbonyl-sulfamidsaure-chlorid <sup>1,2)</sup> , I Uber das Sulfamidsaurechlorid"; 1959; Vol. 92; pg. 509; On CD as filename Graf_20050526162550.pdf.	
	CI	Stig Andre Jacobsen, et al.; "Phenylation of pyrimidinones using diphenyliodonium salts"; J. Chem. Soc. Perkin Trans 1; 1999; pp. 3265-3268; On CD as filename Jacobsen_20050526163157.pdf.	
	Cl	Marc Julia, et al.; "Sur quelques hydroxy et methoxy-3 phenoxy-ethylamines chlorees analogues des tryptamines hallucinogenes"; Chim. Ther. 1965; Vol. 4; pp. 334-343; On CD as filename Julia 20050526162250.pdf.	
	CK	J. A. Kloek, et al.; "An Improved Synthesis of Sulfamoyl Chlorides"; J. Org. Chem; 1976; Vol. 41; pg. 4028; On CD as filename Kloek 20050526162645.pdf.	-
	CL	Yasuhisa Kohara, et al.; "Synthesis and Angiotensin II Receptor Antagonistic Activities of Benzimidazole Derivatives Bearing Acidic Heterocycles as Novel Tetrazole Bioisosteres"; J. Med. Chem; 1996; Vol. 39; pp. 5228-5235; On CD as filename Kohara_20050526162200.pdf.	
	СМ	Henry C. Koppel, et al.; "Pyrimidines. X. (Antibiotics. II) Synthesis of Bacimethrin, 2-Methoxy Analog of Thiamine and Related Alkoxypyrimidines"; J. Org. Chem; 1962; Vol. 27; pp. 3614-3617; On CD as filename Koppel 20050526163054.pdf.	
	CN	C. Maggiali, et al.; "Effetti Anti H1-Istaminici E Antimuscarinici Di Composti 2-E 4-[Benzil-(2-	

Examiner	Date
Signature	Considered

PTO/SB/08a/b (08-03)
Approved for use through 07/31/2006. OMB 0551-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Sut	Substitute for form 1449A/B/PTO			Complete if Known	
		_		Application Number	Not Yet Assigned 5 3 / 4 00
11	<b>NFORMATION</b>	I DI	SCLOSURE	Filing Date	Concurrently Herewith
S	STATEMENT BY APPLICANT			First Named Inventor	Martin Bolli
				Art Unit	N/A
	(Use as many sh	eets as	necessary)	Examiner Name	Not Yet Assigned
Sheet	3	of	3	Attorney Docket Number	A0345.0010

	Dimetilaminoetil)Amino]Pirimidinici"; Farmaco, Ed. Sci.; 1988; Vol. 43; pp. 277-292; On CD as filename Maggiali_20050526163243.pdf.
CO	Jerry March; "Advanced Organic Chemistry, 4 <sup>th</sup> Edition; 1994; pg. 499; On CD as filename March_20050526162122.pdf.
СР	Marvin A. McMillen, et al.; "Endothelins: Polyfunctional Cytokines"; J. Am. Coll. Surg.; 1995; Vol. 180; pg. 621; On CD as filename McMillen_20050525104659.pdf.
CQ	E. D. Morgan; "Synthesis of p-Alkylphenylacetic Acids"; Tetrahedron; 1967; Vol. 23; pg. 1735; On CD as filename Morgan_20050526163434.pdf.
CR	Werner Neidhart, et al.; "Discovery of RO 48-5695: A Potent Mixed Endothelin Receptor Antagonist Optimized From Bosentan"; Bioorg. Med. Chem. Lett.; 1997; Vol. 7; pp. 2223-2228; On CD as filename Neidhart 2_20050526161918.pdf.
CS	Werner Neidhart, et al.; "The Discovery of Nonpeptide Endothelin Receptor Angagonists. Progression towards Bosentan"; Chimia; Vol. 50; pp. 519-524; On CD as filename Neidhart_20050526160756.pdf.
СТ	Richard A. Nugent, et al.; "Pyrimidine Thioethers: A Novel Class of HIV-1 Reverse Transcriptase Inhibitors with Activity Against BHAP-Resistant HIV"; J. Med. Chem.; 1998; Vol. 41; pp. 3793-3803; On CD as filename Nugent_20050526162015.pdf.
CU	Yoshihiro Ogawa, et al.; "Molecular Cloning of a Non-Isopeptide-Selective Human Endothelin Receptor"; BBRC; 1991; Vol. 178; pp. 248-255; On CD as filename Ogawa_20050525110759.pdf.
CV	Eliot H. Ohlstein, et al.; "Endothelin-1 Modulates Vascular Smooth Muscle Structure and Vasomotion: Implications in Cardiovascular Pathology"; Drug. Dev. Res.; 1993; Vol. 29; pp. 108-128; On CD as filename Ohlstein_20050525110638.pdf.
CW	Richard E. Olson, et al.; "Orally Active Isoxazoline Glycoprotein Ilb/IIIa Antagonists with Extended Duration of Action"; J. Med. Chem.; 1999; pp. 1178-1192; On CD as filename Olson_20050526162724.pdf.
СХ	G. M. Rubanyi, et al.; "Endothelins: Molecular Biology, Biochemistry, Pharmacology, Physiology, and Pathophysiology"; Pharmacol. Rev.; 1994; Vol. 46(3); pg. 328; On CD as filename Rubanyi 20050525105453.pdf.
CY	Takeshi Sakurai, et al.; "Cloning of a cDNA encoding a non-isopeptide-selective subtype of the endothelin receptor"; Nature; 1990; Vol. 348; pg. 732; On CD as filename Sakurai_20050525110520.pdf.
CZ	Michael J. Sumner, et al.; "Endothelin ETA and ETB receptors mediate vascular smooth muscle contraction" Brit. J. Pharmacol.; 1992; Vol. 107; pg. 858; On CD as filename Sumner_20050526160142.pdf.
CA1	Matthew J. Tozer, et al.; "4-Chlorobenzyl Sulfonamide and Sulfamide Derivatives of Histamine Homologues: The Design of Potent Histamine H, Receptor Antagonists"; Bioorg. Med. Chem. Lett.; 1999; Vol. 9; pg. 3103; On CD as filename Tozer 20050526163521.pdf.
CB1	von Gunther Weiss, et al; "Herstellung und Reaktionen von N-Monoalkylamidosulfonylchloriden"; Liebigs Ann. Chem.; 1969; Vol. 729; pg. 40; On CD as filename Weiss_20050526162455.pdf.
CC1	Masashi Yanagisawa, et al.; "A novel potent vasoconstrictor peptide produced by vascular endothelial cells"; Nature; 1988; Vol. 332; pg. 411; On CD as filename Yanagisawa 20050525110419.pdf.
CD1	H. Arai, et al.; Nature; 1990; Vol. 348; pg. 730; Will be forwarded at a later date
CE1	A copy of the International Search Report issued for the Parent PCT Application
	i carra a communicación a como conservación de la como

<sup>\*</sup>EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>&</sup>lt;sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

Examiner	Date
Signature	Considered